

B-1
one or more non-mineral nutritional supplements,
a flavor component, and
a calcium source consisting of a hydrate form of calcium sulfate,
wherein said calcium source provides at least about 10% U.S. RDV of
calcium per serving of said calcium fortified beverage composition.

34. (New) A calcium fortified beverage composition consisting of:
purified water,
a flavor component,
a preservative system, and
a calcium source consisting of a hydrate form of calcium sulfate,
wherein said calcium source provides at least about 10% U.S. RDV of
calcium per serving of said calcium fortified beverage composition.

Remarks

The claims are 1, 2, 4-11, 13-20, 25 and 29-34, with claims 1, 4, 6, 8, 10, 20 and 31-34 being independent. Claims 3, 12, 21-24 and 26-28 have been cancelled without prejudice or disclaimer. Claims 1, 4-6, 8, 10, 13, 14, 16-18, 20, 25, 29 and 30 have been amended. New claims 31-34 have been added. Reconsideration of the present claims is respectfully requested.

At the outset, Applicants' attorney would like to thank the Examiner for interviewing the present case on July 9, 2002. During the course of the interview, the cited prior art and the presentation of a translation of the JRC KK reference was discussed. The

Examiner indicated that if the product claims were amended to use "consisting of" language and if the translation of JRC KK was consistent with Applicants' arguments, then the case would be allowable over the presently cited art.

The specification has been amended to correct an obvious typographical error. U.S. Patent No. 5,422,128 was erroneously listed as U.S. Patent No. 5,442,128 at page 2 of the specification. U.S. Patent No. 5,422,128 relates to the use of calcium citrate malate; such use was the focus of the first paragraph of page 2 of the instant specification. Applicants submit that no new matter has been added.

Claims 1, 4-6, 8, 10, 13, 14, 16-18, 20, 25, 29 and 30 have been amended, and new claims 31-34 have been added. Claims 1, 10 and 20 have been amended to include the subject matter of cancelled claims 3, 12 and 21, respectively. Claims 4, 6 and 8 have been amended to be in independent form. All of the independent claims as amended, with the exception of method claim 10, now use the language "consisting of". New claims 31-34 have been added to cover embodiments of the invention which are clearly supported throughout the specification and in order to be consistent in the use of the "consisting of" language; in other words, Applicants' invention is directed to beverages which contain purified water and a calcium source as recited, in addition to optional ingredients such as one or more non-mineral nutritional supplements, a flavor component and a preservative system. The amendments to claims 4, 6 and 8 and the addition of claims 31-34 assure Applicants' protection of intended embodiments of the invention, while making it clear that no other key ingredients would be present. The remainder of the amendments are formal in nature. Applicants submit that all amendments are fully supported by the specification as originally filed and that no new matter has been added.

Claims 1, 20, 27 and 28 stand rejected under 35 U.S.C. §102(e) as being anticipated by Wang. Claims 1-30 stand rejected under 35 U.S.C. §103(a) as being obvious over Braun in view of Wang and Couzy and JRC KK and Lindon. Applicants respectfully traverse these rejections.

Simply put, the present invention is directed to bland, neutral tasting, calcium fortified beverage compositions which contain a hydrate form of calcium sulfate as the sole source of calcium, which provides a level of fortification of about 10% RDV (100 mg/8 oz.). The beverage compositions consist of purified water, the calcium source and, optionally, one or more non-mineral nutritional supplements, a flavor component and/or a preservative system. The present invention is also directed to a method of making such beverages. None of the cited references disclose or suggest the presently claimed invention. Set forth below are Applicants' comments regarding each of the cited references, as discussed with the Examiner in the interview of July 9, 2002.

Wang is not prior art to the present invention. Wang corresponds to Chinese publication no. 1264682, which published on August 30, 2000, and to Chinese application no. 2000-0102052, which was filed on February 24, 2000. The filing date is irrelevant as Wang is not a U.S. or PCT application. Wang is not §102(a) art; it was not known or used by others in this country or patented or described in a publication in this or a foreign country before the invention thereof by applicant. The present application was filed on June 14, 2000; the publication of Wang occurred 2½ months later. Also, Wang is not §102(b) art; it was not patented or described in a printed publication in this or a foreign country or in public use or sale in this country more than one year prior to the date of application for patent. The present application was filed on June 14, 2000; the publication

of Wang occurred 2½ months later. Also, Wang is not §102(e) art; it was not described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2) and (4) of section 371(c) of this title before invention thereof by applicant for patent. Wang is not a U.S. application or a PCT application, therefore §102(e) has no applicability. It is clear that Wang is not prior art to the present invention.

JRC KK relates to a calcium-containing drinking water with a sweet taste. JRC KK corresponds to Japanese patent publication 4-271894. Applicants have had this publication fully translated; a copy of the translation with the translator's notes is included with this paper. While the abstract noted by the Examiner makes reference to the presence of calcium sulfate in the coral-derived material used in JRC KK, it is clear from the full translation of this reference that the coral-derived material contains calcium carbonate and not calcium sulfate. Calcium carbonate (or calcium carbide) is described throughout the specification (paragraphs 5 and 10), claims (claim 1) and table 1. Clearly, JRC KK is irrelevant to the patentability of the present invention because it does not pertain to calcium sulfate.

Lindon is very different from the present invention. First, Lindon is directed to "mineralized" drinking water which necessarily contains strontium, magnesium, calcium and lithium ions as water soluble salts. The present product claims, which use "consisting of" language are closed to the possibility of including any additional ingredients such as additional minerals like strontium, magnesium and lithium. Second, Lindon contains only 60-125 mg/L calcium ions; the present invention is directed to

beverages which contain at least 10% U.S. RDV, roughly 417 mg/L calcium. Third, Lindon prefers the use of calcium chloride; calcium chloride is not suitable for the present inventive purposes, as it would impart a salty taste. Fourth, Lindon contains no disclosure of the steps of present claim 10, i.e., combining a ready to drink beverage with a calcium source which provides at least 10% U.S. RDV of calcium and preserving the solution. Clearly, Lindon does not render the present invention obvious because it would not motivate one of ordinary skill in the art to make a beverage containing calcium as the only mineral in an amount of at least 10% US RDV and supplied solely by calcium sulfate.

Couzy is directed to a calcium and sulfate rich "mineral water" (not necessarily calcium sulfate rich) containing 467 mg/L calcium and significant amounts of magnesium (see p. 1242, table 3). The beverages of the present invention do not contain minerals other than calcium. The use of the "consisting of" language in the product claims closes the claims to the possibility of including any additional ingredient such as magnesium. Additionally, Couzy does not affect the patentability of present process claim 10; the fact that 467 mg/L calcium occurs naturally in a mineral water doesn't necessarily mean that the level can be achieved synthetically; calcium fortification is very tricky (solubility and taste concerns primarily), and there would be no reasonable expectation of success in attempting such a fortification level. What is more, Couzy contains no disclosure of the steps of present claim 10, i.e., combining a ready to drink beverage with a calcium source which provides at least 10% U.S. RDV of calcium and preserving the solution. Clearly, Couzy does not render the present invention obvious because it would not motivate one of ordinary skill in the art to make or provide any guidance in

synthetically making a beverage containing calcium as the only mineral in an amount of at least 10% US RDV.

Braun relates to calcium fortified beverages, but uses calcium sulfate only in small amounts, preferably in combination with calcium chloride, to improve the solubility of other calcium sources in the presence of significant amounts of edible acids. By virtue of the presence of the “consisting of” language in the present product claims, the claims are closed to the possibility of including any additional ingredient such as additional calcium sources and edible acids. Further, Braun contains no disclosure of the steps of present claim 10, i.e., combining a ready to drink beverage with a calcium source which provides at least 10% U.S. RDV of calcium and preserving the solution. Clearly, Braun does not render the present invention obvious because it would not motivate one of ordinary skill in the art to make a beverage containing calcium sulfate as the only calcium source which provides at least 10% US RDV.


In sum, it is clear that none of Braun, Wang, Couzy, JRC KK and Lindon, whether considered alone or in any combination, anticipate or render obvious the present invention. There is simply no disclosure or suggestion of the use of a hydrate form of calcium sulfate alone as a source of calcium to produce a calcium fortified beverage composition (at least 10% US RDV). Accordingly, Applicants respectfully request withdrawal of this rejection.

In view of the foregoing amendments and remarks, favorable reconsideration and passage to issue of the present case is respectfully requested. If, upon consideration of this paper, the Examiner believes there are any outstanding issues, it is

respectfully requested that the Examiner contact the undersigned attorney in an effort to expeditiously resolve such issues.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,


Attorney for Applicants
Registration No. 42,46670

FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, New York 10112-3801
Facsimile: (212) 218-2200

VERSION SHOWING CHANGES MADE TO SPECIFICATION

The paragraph starting at page 2, line 1, and ending at page 2, line 11, has been amended as follows.

A number of calcium sources have received much attention. Most notably, U.S. Patent Nos. 4,851,221 and 5,075,499 relate to calcium citrate and dicalcium citrate lactate compounds and related processes. Furthermore, calcium citrate malate has been extensively investigated as evidenced by U.S. Patent Nos. 5,468,506, 5,445,837, [5,442,128,] 5,422,128, 5,389,387, 5,314,919, 5,232,709, 5,225,221, 5,186,965, 5,151,274, 5,128,374, 5,118,513, 4,994,283, 4,992,282, 4,919,963, 4,872,919, 4,830,862, 4,786,510, 4,737,375 and 4,722,847.

VERSION SHOWING CHANGES MADE TO CLAIMS

1. (Twice Amended) A calcium fortified beverage composition consisting
[essentially] of:

purified water, and

a calcium source consisting of a hydrate form of calcium sulfate,

wherein said calcium source provides at least about 10% U.S. RDV of
calcium per serving of said calcium fortified beverage composition.

2. (Amended) The calcium fortified beverage composition according to
claim 1, wherein the hydrate form of calcium sulfate is calcium sulfate dihydrate.

Claim 3 has been cancelled.

4. (Amended) [The] A calcium fortified beverage composition [according to
claim 1 further comprising] consisting of:

purified water,

one or more non-mineral nutritional supplements, and

a calcium source consisting of a hydrate form of calcium sulfate,

wherein said calcium source provides at least about 10% U.S. RDV of
calcium per serving of said calcium fortified beverage composition.

5. (Amended) The calcium fortified beverage composition according to claim 4, wherein the non-mineral nutritional supplement is chosen from the group consisting of [Vitamins] vitamin A, vitamin D, [E (]tocopherol[])], [C (]ascorbic acid[])], [B (]thiamine[])], [B₂ (]riboflavin[])], vitamin B₆, vitamin B₁₂, [and] vitamin K, niacin, folic acid, biotin, and combinations thereof.

6. (Amended) [The] A calcium fortified beverage composition [according to claim 1 further comprising] consisting of:

purified water,

a flavor component, and

a calcium source consisting of a hydrate form of calcium sulfate,

wherein said calcium source provides at least about 10% U.S. RDV of calcium per serving of said calcium fortified beverage composition.

7. The calcium fortified beverage composition according to claim 6, wherein the flavor component is selected from fruit flavors, botanical flavors, and mixtures thereof.

8. (Amended) [The] A calcium fortified beverage composition [according to claim 1 further comprising] consisting of:

purified water,

a preservative system, and

a calcium source consisting of a hydrate form of calcium sulfate,
wherein said calcium source provides at least about 10% U.S. RDV of
calcium per serving of said calcium fortified beverage composition.

9. The calcium fortified beverage composition according to claim 8, wherein the preservative system is selected from the group consisting of sodium benzoate, potassium benzoate, sodium sorbate, potassium sorbate, EDTA, BHA, BHT, TBHQ, dehydroacetic acid, dimethyldicarbonate, ethoxyquin, heptylparaben, and combinations thereof.

10. (Twice Amended) A method for producing a calcium fortified beverage composition comprising:

(a) combining a ready to drink beverage and a calcium source consisting of
a hydrate form of calcium sulfate to form a solution,

wherein said calcium source provides at least about 10% U.S. RDV of
calcium per serving of said calcium fortified beverage composition; and

(b) preserving the solution to form the calcium fortified beverage composition.

11. (Amended) The method according to claim 10, wherein the hydrate form of calcium sulfate is calcium sulfate dihydrate.

Claim 12 has been cancelled.

13. (Amended) The method according to claim 10, further comprising the step of adding one or more non-mineral nutritional [supplement(s)] supplements prior to step (b).

14. (Amended) The method according to claim 13, wherein the one or more non-mineral nutritional [supplement(s)] supplements is chosen from the group consisting of [vitamins] vitamin A, vitamin D, [E (]tocopherol[]), [C (]ascorbic acid[]), [B (]thiamine[]), [B₂ (]riboflavin[]), vitamin B₆, vitamin B₁₂, [and] vitamin K, niacin, folic acid, biotin, and combinations thereof.

15. The method according to claim 10, wherein step (b) comprises subjecting the solution to a pasteurization process.

16. (Amended) The method according to claim 15, wherein the pasteurization process is chosen from the group consisting of hot-filling, aseptic packaging, ozonation, radiation, UV light, high pressure, membrane permeation, pulsed electric field, sonication, [or] and combinations thereof.

17. (Amended) The method according to claim 10[,] further comprising the step of adding one or more flavor [component(s)] components prior to step (b).

18. (Amended) The method according to claim 16, wherein the one or more flavor [component(s)] components is chosen from the group consisting of fruit flavors, botanical flavors, and mixtures thereof.

19. The method according to claim 10, wherein the ready to drink beverage is purified water.

20. (Twice Amended) A beverage composition consisting [essentially] of:
[a nutritionally significant amount of calcium and] purified water, and
at least about 10% U.S. RDV of calcium per serving of said beverage
composition.

wherein the beverage composition is produced by combining purified water
and a calcium source consisting of a hydrate form of calcium sulfate [and purified water] to
form a solution.

Claim 21 has been cancelled.

Claim 22 has been cancelled.

Claim 23 has been cancelled.

Claim 24 has been cancelled.

25. (Twice Amended) The beverage composition according to claim 20,
wherein the hydrate form of calcium sulfate is calcium sulfate dihydrate.

Claim 26 has been cancelled.

Claim 27 has been cancelled.

Claim 28 has been cancelled.

29. (Amended) A method of providing at least about 10% of the U.S. RDV
of calcium to a subject comprising administering to the subject the calcium fortified
beverage composition of claim [3] 1.

30. (Amended) A method of providing at least about 10% of the U.S. RDV
of calcium to a subject comprising administering to the subject the beverage composition
of claim [21] 20.

31. (New) A calcium fortified beverage composition consisting of:
purified water,
one or more non-mineral nutritional supplements,
a flavor component,
a preservative system, and

a calcium source consisting of a hydrate form of calcium sulfate,
wherein said calcium source provides at least about 10% U.S. RDV of
calcium per serving of said calcium fortified beverage composition.

32. (New) A calcium fortified beverage composition consisting of:
purified water,
one or more non-mineral nutritional supplements,
a preservative system, and
a calcium source consisting of a hydrate form of calcium sulfate,
wherein said calcium source provides at least about 10% U.S. RDV of
calcium per serving of said calcium fortified beverage composition.

33. (New) A calcium fortified beverage composition consisting of:
purified water,
one or more non-mineral nutritional supplements,
a flavor component, and
a calcium source consisting of a hydrate form of calcium sulfate,
wherein said calcium source provides at least about 10% U.S. RDV of
calcium per serving of said calcium fortified beverage composition.

34. (New) A calcium fortified beverage composition consisting of:
purified water,

a flavor component,
a preservative system, and
a calcium source consisting of a hydrate form of calcium sulfate,
wherein said calcium source provides at least about 10% U.S. RDV of
calcium per serving of said calcium fortified beverage composition.

NY_MAIN 308329v1